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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,079	09/20/2001	Kirk Patrick Seward	07043-091001	5103
22434	7590	08/11/2004	EXAMINER	
BEYER WEAVER & THOMAS LLP			THOMPSON, MICHAEL M	
P.O. BOX 778			ART UNIT	
BERKELEY, CA 94704-0778			PAPER NUMBER	

3763

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/961,079

**Applicant(s)**

SEWARD ET AL.

**Examiner**

Michael M. Thompson

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 8-25 is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03-19-2004</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (6,009,877). Edwards teaches a method of interventional surgery comprising inserting an actuator within a body operating the actuator to cause a needle to move in a substantially perpendicular direction relative to the wall and delivering a therapeutic or diagnostic agent from the needle, wherein the therapeutic agent is a pharmacological agent or diagnostic (column 7).
3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Barath et al. (5,112,305). Barath teaches a method of interventional surgery comprising inserting an actuator within a body stopping adjacent a target region the actuator including an expandable section incorporating a needle and operable between an unactuated furled state and an actuated unfurled state wherein when the device is in the unfurled state the needle moves in a substantially perpendicular direction relative to the wall of the vessel, wherein the causing step includes supply an activating fluid or gas to cause expansion and deflation and delivering a therapeutic or diagnostic agent from the needle, wherein the therapeutic agent is a pharmacological agent or diagnostic. (columns 2, 3)

*Allowable Subject Matter*

4. Claims 6 and 8-25 are allowed.

*Response to Arguments*

5. Applicant's arguments filed 03/19/2004 have been fully considered but they are not persuasive. In addressing Applicant's arguments with respect to claims 1-5 it is the Examiner's position that the rejections of both Edwards ('877) and Barath et al. ('305) fully anticipate the claimed limitations. On the outset, it should be noted that Edwards does in the least teach the treatment of a diagnostic and potentially a therapeutic. In column 7, lines 48-59, Edwards states that suitable echogenic markers such as gas filled particles as shown in U.S. Patent No's 5,688,490 and 5,205,287 thereby incorporating those teachings as a reference to the delivery agents intended by Edwards. An examination of the references cited by Edwards would include diagnostic agents used for therapeutic purposes. The broadest interpretation of claim 1 does not appear to be limited to an actual hollow needle that penetrates the tissue or delivering the fluid from the lumen of the hollow needle to the tissue. In making this distinction it would seem that any device that sufficiently penetrates the tissue after the delivery of a therapeutic or diagnostic fluid would sufficiently satisfy the limitations of the claims. Applicant only recites that the agent is delivered by the needle to the target region. With respect to the claims which depend from claim 1 it is the Examiner's position that the limitations of claims 4-5 are met in light of the teachings supra in the Edwards rejection.

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6. In addressing the rejection of claims 1-4 in light of Barath et al. ('305) it is the Examiner's position that the Barath device teaches expansion and deflation of the device in order to control the needle/protrusions. (Claims 1-3) For instance, as recited in column 3 Barath states under the description of Figures 3-5 that the tubular extensions will penetrate the vessel wall for administration of the appropriate agent. Lastly, it is the Examiner's position that the agents recited in Barath anticipated claim 4.

### *Conclusion*

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

MT



August 06, 2004



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